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| 09/772,394 | 01/30/2001 | Peter Stangel | MG-001-US | 1200 |

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| EXAMINER |
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BUI, KIM T

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| ART UNIT | PAPER NUMBER |
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3626

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,394

Applicant(s)

STANGEL, PETER

Examiner

Kim T. Bui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/14/01&8/30/01.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In the present application, the provisional application number has not yet been provided in the specification or in the oath/declaration.

Specification

2. The disclosure is objected to because of the following informalities: On page 6 of the specification, Fig. 2A and Fig. 2B should be included in the "Brief description of the drawing" section. On page 12 of the specification " Fig 2" on line 4 should be "Fig. 2A"

Appropriate correction is required.

Claim Objections

3. Claim 19 is objected to because the claim does not start with a capital letter. Each claim should begin with a capital letter and end with a period. See MPEP 608.01(m).

Claim Rejections - 35 USC § 101

4.. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-14, 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena), or software that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts. The body of the claim(s) must recite how the technological art is employed to produce a useful, concrete and tangible result in a non-trivial manner.

(A) In general, the claims recite a collection of software, in particular, claims 1-14, 19 recite the interfaces and modules, the steps for entering data, for providing verification results that do not involve, use or advance the technological arts. The recited database in the claims may be a file storage that does not have to be in a computer, e.g., a file cabinet.

In addition, for a claimed invention to be statutory, it must produce a useful,

concrete, and tangible result. In the present case, the claimed invention recited in claims 1-8, 12-14, 19 produces a method for navigating and determining authorization level (i.e., repeatable) used in medical diagnosis clinical record generating (i.e., useful and tangible). However, claims 9-11 recite the inputting steps only, and there is no output. These claims, therefore, fail to produce a useful, concrete and tangible result.

Although the recited process in claims 1-8, 12-14, 19 produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-14,19 deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

6.. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7,9-14,19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) As per claim 1, "the directed-to fields" on lines 11-12 lacks clear antecedent basis; " the authorization level" on lines 10-11 lacks clear antecedent basis.

(B) As per claim 7, "the user screens" on line 3, "the user interaction" on line 8, "the data selections" on line 10 lacks clear antecedent basis;

(C) As per claim 9, "the system" on line 2 lacks antecedent basis;

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(D) As per claim 12, 'the selection of a system group' on line 2, "said diagnosis element" on line 3, "said element selection" on line 4, 'the selection of findings and parameters for said system group' on line 9 lack clear antecedent basis.

(E) As per claim 19, " the selection items in the criteria selection interface" on line 7 lacks clear antecedent basis:

(F) As per claims 1,7, the claims recite a system, however, there is no structural limitation(s) in the body of the claims to support the recitation of the system (i.e., "the computer implemented system", and "the medical data utilization system") recited in the preamble.

(G) As per claim 12, the claims recites an interface with "two portions" and "two areas", it is unclear if applicant seeks protection for a method, an apparatus, or an article of manufacture.

Dependent claims 2-6, 10-11,13-14 incorporate the deficiencies of the claims they depend on and are therefore rejected.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 8-11,15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Provost et al (6341265 B1).

(A) As per claim 8, Provost discloses a method for submitting clinical record (i.e. claim payment) for automated processing, comprising:

a. providing a selection interface, adapted to facilitate the user selection of one of a plurality of data values. Provost et al, Figs 2,3, col. 9, lines 15-35, lines 53-58, col. 11, lines 29-35.

b. receiving a selection (i.e. diagnosis code, dollar amount) from the selection interface. Provost et al. figs 2,3, col.9, line 53 to col. 10, line 3, col. 11, lines 29-35.

c. providing data fields in response to the selection, data fields includes quantified data field (i.e. dollar amount) associated with objective criteria (i.e. treatment code), the data fields are evaluated for automated processing of the clinical record .Provost et al. col. 9, lines 65 to col. 10, lines 16, Fig. 3, elements 46, 52, 54,50, 56, col. 11,lines 19-49.

(B) As per claim 9, Provost et al discloses a method for entering medical diagnosis data comprising:

a. entering a diagnosis into the system. Provost et al. fig. 2,3, col. 9, lines 15-18.

b. entering a criteria into a system, the criteria corresponding to a rule required for authorizing a diagnosis, the criteria associated with at least a finding. Provost et al, col. 9, line 44 to col. 10, line 16.

c. entering a finding (i.e. nature of illness) into the system. Provost et al, col. 9, lines 38-40.

(C) As per claim 10, addition data corresponding to finding (i.e., nature of illness) such as patient information, treatment code and charges can be entered according to Provost et al. Provost et al., col. 9, lines 44-46, col. 8, lines 45-55, col. 11, lines 25-28.

(D) As per claim 11, Provost teaches that the user can request for resources provided by server, as well as addition request selection interface to resubmitted denied procedures. Provost et al., col. 8, lines 1-15, col.11, lines 5-18.

(E) As per claim 15, Provost et al. discloses a method for processing medical procedure data for insurance or HMO (i.e. healthcare organization), comprising:

- a. establishing an Internet site that provides forms that facilitate the entry of procedure data. Provost et al. Figs 2, 3, col. 3, lines 39-55, col. 6, lines 47-52, col. 12, lines 14-29.
- b. configuring the forms to apply a first set of rules for authorizing procedures (i.e. beneficiary, validity, accuracy). Provost et al, Figs. 2, 3, col. 6, lines 47-62, col. 8, lines 21-32, col. 8, lines 59-67, col. 4, lines 7-21.
- c. receiving medical procedure data from medical care provider interacting with the Internet site. Provost, col. 3, lines 40-55, col. 4, lines 7-21, col. 6, lines 47-67.
- d. processing the received data automatically in accordance with first (i.e. beneficiary, validity and accuracy) and second set of rules (i.e. rules for determining the types of diagnosis and treatment that are covered /approved by the insurance or HMO). Provost et al. col.10, lines 1-24.

(F) As per claim 16, Provost et al teaches the both first and second set of rules are used as criteria to determine whether or not the procedures are approved. Provost, col. 10, lines 9-12, col. 10, lines 17-19.

(G) As per claim 17, Provost teaches that if an authorization fails (i.e. user is not a beneficiary), the system informs the heath care provider the results so that the

healthcare provider can promptly learn of the status before proceeding.(i.e. filling and submitting forms). Provost et al. col. 8, line 64 to col. 9, line 6.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Provost et al. (6341265).

(A) As per claim 7, Provost et al. discloses a medical data utilization system, comprising:

- a. a user interface (i.e. display) to facilitate the submission of data to the system, the user interface associated with forms database that is used to generate user screens by which data is entered. Provost et al., Figs 2,3, 4A, col. 3, lines 40-50, col. 8, lines 22-32.
- b. a forms storage device (i.e. database) for storing forms and controls employed to facilitate the generation of user screens. Provost et al. Fig. 1, col. 8, lines 25-32.
- c. a selection database for providing the data selections that should be available to a user. Provost et al. col. 9, lines 10-14, col. 9, lines 53-58.
- d. a verification module operatively coupled to the interface for processing data received from the interface, the verification determines a level of authorization (i.e.

beneficiary status or approved procedures) and criteria compliance based on entered data. The verification module is associated with database for storing criteria/rules used to determine authorization and compliance (i.e. beneficiary, accuracy, completeness, fraud, and approved / rejected). Provost et al. col. 7, lines 29-51, col. 8, line 64 to col. 9, line 6, col. 10, lines 2-22.

Provost fails to explicitly recite the navigation module. However, it is readily apparent that a navigation keys and bar are needed for controlling cursor movement in order to enter data into the designated fields of the formatted forms, as well as to transmit URL for accessing resources provided by the server. Provost et al., Figs 2, 3, col. 8, lines 1-15. One having ordinary skill in the art at the time of the invention would have found it obvious to include navigation module with the motivation of facilitating the entering of data and accessing of resources. Provost et al. col. 8, lines 1-15, Figs. 2, 3.

12. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Provost et al. (6341265) in view of Jacobs et al. (6049749).

(A) As per claim 1, Provost et al. discloses a patient medical record management system comprising:

a. data entry interface for entering data corresponding to medical diagnosis. Provost et al., Figs 2, 3, col. 6, lines 63-67, col. 9, lines 14-20.

b. selection interface for selecting at least a diagnosis. Provost et al. Figs 2, 3, col. 9, lines 45-58, col. 6, lines 63-67.

c. a verification module for determining status authorization and diagnosis authorization. Provost et al, col. 10, lines 2-22, col. 8 line 59 to col. 9, line 15.

Provost fails to explicitly recite the navigation module. However, it is readily apparent that a navigation key and bar are needed for controlling cursor movement in order to enter data into the designated fields of the formatted forms, as well as to transmit URL for accessing resources provided by the server. Provost et al., Figs 2, 3, col. 8, lines 1-15. One having ordinary skill in the art at the time of the invention would have found it obvious to include a navigation module with the motivation of facilitating the entering of data and accessing of resources. Provost et al. col. 8, lines 1-15, Figs. 2,3.

Provost discloses authorization for diagnosis and treatment procedures (Provost et al., col. 10, lines 1-24), but fails to expressly recite level of diagnosis. However, a system for medical decision making for determining appropriate level of diagnosis /care is well known as evidenced by Jacobs et al. Jacobs et al., the abstract, col. 3, lines 1-45, col. 4, lines 30-55. It would have been obvious to one having ordinary skill in the art at the time of the invention to include level of care/ diagnosis with the motivation of providing verification and feedback to physician whether or not an intended course of action is medically appropriate and thereby improving the selection of a proper treatment plan. Jacobs et al, col. 2, lines 38-42, col. 2, line 65 to col. 3, line 12.

(B) As per claims 2,3, 5,6, Provost teaches the selection of codes corresponding to selected diagnosis wherein the authorization of the diagnosis depends on whether or not the codes defining the types of diagnosis/treatment that are approved by an insurer or a HMO. Provost also discloses different levels of criteria and rules for authorizing a status of a user, for verifying accuracy and completeness of inputted data, for diagnosis authorization. Provost et al., col. 8, line 59 to col. 9, line 5, col. 10, lines 2-22. Provost

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fails to expressly recite the diagnosis level. This, however, suggested by Jacobs et al. See the abstract, col. 3, lines 1-45, col. 4, lines 30-55. It would have been obvious to one having ordinary skill in the art at the time of the invention to include level of care/ diagnosis with the motivation of providing verification and feedback to physician whether or not an intended course of action is medically appropriate and thereby improving the selection of a proper treatment plan. Jacobs et al, col. 2, lines 38-42, col. 2, line 65 to col. 3, line 12.

(C) As per claim 4, Provost teaches that the patient claim forms 12 A and 12B can be separate forms displayed to the user or can be portions of a single display. Provost et al. col. 9, lines 19-25.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al. (6049794).

(A) As per claim 19, Jacobs et al discloses a method for providing an indication of authorization level to a user of a utilization system that facilitates the submission of medical diagnosis/treatment data comprising:

a. providing a selection interface to select a diagnosis criteria. Jacobs et al., col. 3, lines 1-20, col. 5, line 50 to col. 6, line 60.

- b. receiving diagnosis related data from a user. Jacobs et al., col.3, lines 1-20, col. 6, line 60.
 - c. applying verification rules to the received data. Jacobs et al., col. 3, lines 1-3, col. 4, lines 51-52,
 - d. providing an indication of verification results (i.e., criteria met, criteria not met) within the selection items in the selection interface to indicate criteria authorization level. Jacobs et al. Figs 15-18, col. 3, lines 1-20, col. 8, lines 42-48.
15. Claims 12-14, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (6049794) in view of Provost et al. (6341265).
- (A) As per claim 12, Jacobs et al discloses a system for entering and displaying the authorization for diagnosis/ treatment plan, comprising:
- a. a portion of display for facilitate the selection of a system group (i.e. criteria set). Jacobs et al, col.5, lines 50-68, col. 3, lines 1-20. Figs 5-8.
 - b. a portion of display selection or enter of diagnosis element (i.e. procedure or body system) wherein displayed data changes in response to the selection. Jacobs et al, col. 3, lines 1-20, col. 6, lines 1-4, lines 54-61, Figs. 5-8.
 - c. a display area within the selection of diagnosis element for displaying parameters and findings (i.e. indications and criteria points). Jacobs et al, col. 3, lines 1-20, col. 4, lines 30-55, col. 7, lines 20-40, col. 9, line 8-33, Figs 9-10, 15-18.
 - d. data entry means for selecting of findings and parameters. Jacobs, col. 3, lines 1-20, col. 9, lines 1-28.

Jacobs teaches multiple screens, and fails to expressly recite a single interface. However, it is well known to provide multiple windows within a display. In addition, Provosts et al. teaches the information displayed on separate screens can be combined so that multiple display portions can appear on a single display, and that specific fields can be varied from one implementation to another. Provost et al, col. 9, lines 19-35. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide a single screen as suggested by Provosts with the motivation of providing flexibility for the user in the design /creation of charts/forms. Provost et al. col. 9, lines 30-35.

(B) As per claims 13,14, Jacobs discloses a plurality of indications and findings, and data entry is adapted to enter more than one findings. Jacobs et al, Figs 9-11, col. 7, lines 20-25, col. 9, lines 8-24.

(C) As per claim 18, Jacobs et al discloses a method for submitting medical diagnosis/treatment data comprising the steps for:

- a. providing element selection interface for selecting element (i.e. criteria set) associated with diagnosis. Jacobs et al, col.5, lines 50-68, col. 3, lines 1-20. Figs 5-8.
- b. providing system group interface for selecting system group (i.e. body system) of the selected element. Jacobs, col. 3, lines 1-20, col. 6, lines 1-4, Figs. 5-8.
- c. providing parameter selection interface for selecting parameter (i.e. test) of the selected group. Jacobs, col. 3, lines 1-20, col. 4, lines 30-55, col. 7, lines 20-40. Fig. 9
- d. providing finding selection interface for selecting finding (criteria points) of the selected parameter. Jacobs , col. 3, lines 1-20, col. 4, lines 30-55, col. 9, line 8-33.

Figs 10,15-18.

Jacobs teaches multiple screens, and fails to expressly recite a single screen and single line display. However, it is well known in the art to provide multiple windows within a display. In addition, Provosts et al. teaches the information displayed on different screens can be combined so that multiple display portions can appear on a single display, and that specific fields can be varied from one implementation to another. Provost et al, col. 9, lines 19-35. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide a single screen as suggested by Provosts with the motivation of providing flexibility for the user in the design /creation of charts/forms. Provost et al. col. 9, lines 30-35.

Conclusion

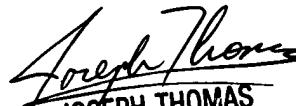
16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "Disease Management System" (6234964 B1); "System For Treatment Planning And Assessment " (6484144 B1); "Medical Record Management" (5974389); "A Web-Enabled Framework For Smart Card Application In Health Care" Chan et al, Sept 2001, Communications Of The ACM, 44, 9, 76, Dialog File 149, Acc. no. 02021813.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim T. Bui whose telephone number is 703-305-5874. The examiner can normally be reached on Monday-Friday from 8:30A.M. to 5:00P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KTB
02/17/2005.


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